

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

ANIMAL FEED SAFETY SYSTEM
PUBLIC MEETING

Wednesday, September 24, 2003

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P R O C E E D I N G S

MS. DUNNAVAN: Okay, I think I have almost everybody in. We have a lot of good info, what we've been hearing from the discussion groups, and now we're going to spend a couple of hours sharing some of that information that you had in your particular group with the rest of the group.

I'd like to start with group 1A. Who's the spokesperson for 1A? Okay, I want you to come up to the front. You can either come up to the podium or hold the mike. I'd like to hear you provide your group's answers for questions 2 and 3. You did not do question 3? Okay, how about questions 2 and 4? Sorry about that. Questions 2 and 4. And read the questions so that everybody knows what you're answering.

For those of you that weren't here yesterday I'm Gloria Dunnavan. I'm the director of compliance, FDA Center for Veterinary Medicine, and I'm just going to moderate this today but really you all are going to do the talking. I'd like to ask each person when you get up to report from your group, will yourself so that we know who the spokesperson is.

MR. FROST: I'm Tom Frost. I'm with Gold Kist in Atlanta, Georgia and I volunteered, I guess, for this position. You all know how that goes, don't you?

Number 2: What do you think are basic elements of an animal feed safety system, remembering that this will be for all feed and feed ingredients--commercial manufacturers, distributors and on-farm mixers?

We discussed these basic elements and narrowed it down really to hazard assessment and analysis and resolved that quite simply the HACCP program fits quite well into this program, with the seven points of HACCP that you're all familiar with.

In addition to that, we pointed out a couple of issues that are of concern to us, the first being funding. If this is to involve inspections or follow-up training, then we're talking about a major funding deficiency when you talk about not only licensed operations but on-farm mixers. This, I guess, was a theme throughout our discussion today, is the scope that we're dealing with.

We also emphasized that everything that we do in this plan needs to be science-based. We find that as a

very critical part of what we do. Many of us are scientists and we recognize that the FDA looks at that, as well, and we want to emphasize that these programs that are discussed are science-based.

Questions? Was that too brief? Just one at a time. Or do they get to ask questions?

I'm on to number 4. The notice of meeting identified seven items that FDA has considered as possible elements of an animal feed safety system. Please answer questions 4A through H for the following element: a thorough analysis of manufacturing and distribution for each product. Should I read through each one of those items?

A, how much of this are you doing as a firm right now or how much of this are you seeing during inspections of feed and feed ingredient manufacturers and distributors? Give some examples.

I'll start with item A. Our group consisted of integrators, such as myself, consisted of some state officials and federal officials, some commercial feed companies, and we concluded that licensed and--we were searching for a word, whether larger fit or not doesn't

seem to be quite the answer we wanted, but larger firms or licensed firms already have in place a fully operational quality assurance program.

When we talk about a thorough analysis of manufacturing and distribution, we're talking about an evaluation of what we make and what we send out and these programs are driven by liability. Companies that recognize that liability are fully aware of monitoring, whether it be chemical or biological or physical contaminants, that we are checking ingredients. We're checking feeds that go out and ingredients that come in. We're checking the process and making sure that we are doing what our program outlines it to be. Again we recognize that liability is a major driver, our liability to customers.

We also discussed on this item that there are many state programs that are not sufficiently funded to handle this kind of program. There are a few states that do have a program, like the presentation we had yesterday from California, but most states it appears--that's a broad statement for a few people we had in our group but

it seems that the state system is not funded sufficiently to look at on-farm feed mixing systems.

The scope again is a huge scope and I think all of you must have gotten into this part of your discussions, as well, that if we talk about a program such as this, to inspect it, to see that it's operating correctly might be one thing with licensed firms like we're doing now, but to expand that and to include it with all of your on-farm groups, it's a very significant undertaking that's going to require a good deal of funding and training.

A couple of quick examples in terms of liability and what firms are doing currently. We broke this down into systematic and compliance analysis. A system analysis would really be referred to as your quality assurance program, what you are doing to maintain the quality as you manufacture from day to day. Quality control or compliance aspect of this is more related to what you are doing to meet GMPs. Again your larger firms already are doing this in a very efficient manner and we'll talk about costs here in just a few minutes.

A couple of examples. Is the proper feed being delivered to the farm? We know we have compliance issues of making sure that medications are withdrawn, the proper time frame. Medications cost money. We want to make sure they're not delivered to the wrong farm. We want to make sure that they're not fed to birds being prepared for slaughter. This is a company liability issue. Yes, it's a federal compliance issue but it's also a liability that we make sure that our customers are getting quality products.

So we audit our feedmills on a regular basis to ensure that feed is being delivered as it's supposed to be delivered, that it's the proper feed on the feed ticket and that it's delivered like it's intended to be done.

Finished feeds are also analyzed on a regular basis at most of our firms and when I say most, I'd say as an industry. Your federally licensed feedmills--I speak for my company and for others--we have an obligation to make sure that these feeds are being sent out properly. Because my company does not sell feed, we do not have a label to maintain a minimum protein

guarantee, for example, but we have a bird performance minimum that we have to maintain. Birds needs to be given the protein we designed for them to receive at that time or they don't perform properly. We have to keep the birds healthy and strong.

But from a commercial feed standpoint, those labels, those minimums have to be met on protein, calcium, phosphorus, so there's a liability for all companies that produce feed to keep it within those minimums. So samples are taken regularly, daily, of a manufacturing process to make sure that feeds are being manufactured properly, that they come out like they're supposed to.

Also in a systematic approach, pellet quality is maintained and monitored daily--temperatures on the pellet mill. The percent pellets in the feed is very important if you're selling feed or if you're producing feed for your own stock. Feed quality is monitored regularly and these are programs that are already in place.

Item B. Is it formal--i.e., written policy and procedures--or informal? Again the common theme is

licensed corporations that are taking the liability, dealing with the liability of producing food products, it is written, it is formal, and there are policies and procedures in place. As you filter on down to the on-farm mixers I feel that it's not in place. As our group discussed, our state people emphasized the programs or the lack of programs and funding that they have to deal with, so it is apparent that some of that is not occurring on a small scale, not occurring on a large scale on small farms. Does that sound a little better?

Item C. Would this involve training? What kind of training would be best for this and how often? One of the issues that came up toward the end of our discussion--this is a kind of multi-pronged answer, if you're prepared for this--larger firms, additional training is not required. Training is already taking place. At feedmill levels quality assurance personnel are being trained on a regular basis.

State operations, when they have personnel and funds, training is taking place, but again there's a major loophole that appears when you get down to the farm level of on-farm feed mixing operations.

We also discussed a great avenue of university extension programs to help us in this training operation. That becomes a real significant input from universities. Provided they have the funding, and it appears that most do, extension services are a real strength to help with farmers in dealing with these issues, whether it comes to training and follow-up, but most of the industry I would recommend to you is fully involved in training of these programs already.

I left off one of those prongs. Let me bring it up now. Item D, would this involve the purchase and use of new equipment and/or software? Consider this answer for both industry and government.

We discussed the word "this" in that sentence. Does what involve the purchase of new equipment and/or software? From the point of view of an established company it would not involve any new equipment or software. It's already being done. Training and education and compliance is being met, so the answer would be no. If it involves more than what is being done in an established quality control program, then new equipment and software may be necessary.

We discussed pathogen levels in feed and how much of an impact is that on the industry. If this program wandered into pathogen-negative feed as an issue for food safety, then that would require a significant increase in equipment and cost for any company. And we would again emphasize that we are a science-based organization, that we make decisions on these kinds of things based on science.

We discussed somewhat the science behind pathogens in feed and how much data do we have and how much is in feed and how critical is it? You and I don't eat hog feed and we don't eat poultry feed and we don't eat these things ourselves. We feed them to animals that are then processed and cleaned and through education, hopefully properly cleaned and cooked, but that question does depend significantly on whether or not we wander into that direction of pathogens.

Item E, the kinds of costs you think this would entail. Consider this answer for both industry and government. We arrived at a figure of about 30 cents, 25-30 cents a ton on a quality assurance program at a feed company. Those in our group arrived at that number

as fairly representative of what we're doing right now. That's a significant cost if you're not doing anything. For those that are not involved in a quality assurance program at all, that's a pretty significant cost.

If it expanded to a pathogen issue, a speaker yesterday addressed the need to include pathogen or Salmonella-negative feed from beginning to end, including the farm and we see this as a real concern to us because we do not own these farms. Farms are owned by individuals and we do not have control over how clean they keep their farm. It becomes rather redundant to send out a sterile feed to a farm that you and I know is not sterile and it becomes even more redundant to realize that whether or not someone gets food poisoning is not dependent on feed; it's dependent on how they cook their meat and take care of their own food source.

So the costs involved, if that was to become part of this program, would definitely put many out of this business altogether if that was to be driven. I suppose it could be done with many years of focus but it would be a significant cost.

F, G, and H we skimmed through a little bit lightly in our group. I will discuss H briefly. Are current enforcement tools adequate? I think we agreed that as a group FDA oversight over our licensed feedmills at this time is already lacking in funds, so if this was to become part of a more broad scope it would definitely require more funds and the current enforcement would not be adequate.

That's really all that I have at this time on items 2 and 4. If you have questions, I'll be happy to answer them. Just one at a time.

MS. DUNNAVAN: We do have a couple of minutes. If any of you do have any questions you want to ask out loud, we've got people that will give you a mike so everybody can hear. If you don't want to ask it out loud we do have a question and comment cards in your packets and we would welcome questions or comments on anything you're hearing today that would help us.

Seeing no hands, thank you very much.

I would like to, before you're completely off the hook here, I would like to ask group 1B if you had

anything you wanted to--who's the spokesperson for 1B?

Are we in the room yet? Okay.

Did you have anything that you wanted to add to question 2 or 4? Great, okay. Thank you very much.

[Applause.]

MR. COSTIGAN: My name is Tim Costigan with Prince Agri Products and unlike Dr. Frost, I didn't volunteer; I was volunteered, so a slight difference there.

You want us to do questions 2 and 4? Actually, we did not do 2. Our instruction was 1, 3 and 4.

4 is kind of a long list. We have the same questions to answer but a thorough analysis of manufacture and distribution for each product, you know, how much of this are you doing as a firm and how much of this are you seeing during inspections of feed, et cetera?

What we're seeing out there is that there are risk-based systems in place for ingredients and for some of the suppliers. There's also formal and informal HACCP being performed at numerous companies that are involved in this. There's also companies doing GMPs and expanded

GMPs, but then there are also some companies who are doing nothing. So it's a wide range. It's truly across the board there.

Under the question of is it formal written procedures and policies, again some have formal documentation and some have no documentation. So again it's across the gamut there.

Question C, would this involve training, it was a definite yes. It would involve training with industry, with government, and everyone else involved in the feed industry, all the way from the suppliers through the manufacturers of the feed down to the level of where the feed is actually consumed and then on to the processor, so there would be training across the board there. It needs to be on-going training. It needs to be training that's specific to the sector that's involved, so it has to be different for perhaps an ingredient manufacturer than for a feed company than for someone who's feeding cattle or feeding poultry, et cetera, and then to the processors beyond that.

But truly they're looking if a system is comprehensive it has to involve everything from the

sources all the way through where the meat hits the table there, so to speak.

Would this involve purchasing of new equipment and/or software? That's a difficult question to answer because again the needs are quite varied, but the ready answer was that first off, if you're trying to control situations there are some that are uncontrollable and would require equipment to do testing prior to unloading of materials; for example, some of the micotoxin concerns with feedstuff, with corn, et cetera. You're not able to 100 percent control that, so you would have to do inspection at the time of unloading, so a fast, cheap assay method that's accurate would be a great help there.

There's other things that cannot be done that way and you really have to work with your sources and your suppliers to try and resolve those, but there would be expenses according to trying to control those things, keep those out of the system.

Training becomes another large expense, both personnel, adding personnel to take care of extra requirements, but also looking at Internet training and then all the training materials being multilingual. So a

number of the inspectors said if I take that information down into a feed plant, if it's in English only a good majority of the people we have to deal with won't understand it; it has to also be in Spanish, perhaps in German. So looking at multilingual training materials and having training available. The university was one application, also training for corporations through third parties, et cetera, but those materials would need to be coordinated and then I'm sure there's a cost associated with that.

Question E was what kind of costs would this entail? We started out by talking a little bit, so we decided that probably the only consensus we were going to come to is that we're certain it wouldn't cost a few hundred dollars. We assume that it's not going to cost a few thousand dollars. At a few million dollars we had a few people buy in. When you got up into the billion dollars, most of the people had pretty well said it's somewhere in the millions to the billions of dollars.

So it is very expensive and, in fact, all that cost is transferred to the cost of the product going to

the consumer, so the food itself is going to have to bear the cost of that.

Question F, what kind of assurances would you need to establish to demonstrate this is functional? Would you need a consultant to help? Would you need a third-party inspection to establish assurance? Would you need on-going sampling programs? And how would federal licensing and registration help?

So answering all of those, we're looking at objective evidence and documentation being the key things that have to be in place. The government's ability to redirect efforts to noncompliant feed and farms would be an advantage. It would be an economic advantage for companies to put programs, comprehensive programs in place.

So the economic advantage would basically help you establish a program and then the government agencies could come through and review that program or third-party companies could come in and review that program and then that information would basically save them the trouble of going out and doing a very comprehensive study.

If you're going to use third parties, they would have to be linked to the regulatory agencies and possibly accredited by the regulatory agencies. I know the regulatory agencies are somewhat apprehensive about trusting the opinion of a third party and I can certainly understand that.

So the need there would be if a third-party registration is brought in it would have to be accepted both by regulatory and it would have to be effective for the company that's bringing that party in.

And the question is sampling necessary? Absolutely and I think the question becomes how do you direct your sampling and your analytical efforts? And that needs to be directed truly by the risk base. In other words, if you're taking a risk-based attitude toward your whole protocol, you're going to be looking for problems in the food and in transferring those back through the cycle until you find the source of that and eliminating it. So the use of sampling and testing to pursue those matters and to limit the exposure is certainly where the dollars need to be spent.

Question G, how do you envision risk for both human and animal health being introduced to AFSS? Should risks be identified by industry or government, or both? We feel that the risks should be identified by both but they need to be scientifically-based. Any decisions that are made or anything that is pursued cannot just be conjecture. It has to have a scientific basis and the levels that are set need to be realistic, and any source, including whatever the source may be, anything across the board.

And also there seems to be some breakdown in interdepartmental agencies and sharing of data where sometimes one department has data and the other one's not necessarily aware of it. So opening up some of those channels would certainly put this process on a faster track.

And H, are current enforcement tools adequate? There was quite a bit of discussion on that one. The answer initially was yes but then there were a couple of conditions put upon that. One of them was that they needed better communications. There are tools out there. There are ways to pull those services together and to

make those more effective and to make better utilization of the efforts both on an industry side and on the regulatory side, but communications need to improve for that to happen.

The second thing was that there's a lack of enforcement in some situations where the government agencies do not have the ability to take action that they feel is necessary so they said that they're a little bit short on that end, as well.

I don't know if any of the members of the group have other comments that I missed. Maybe none of them showed up. I'm on my own.

Does anyone have any questions?

QUESTION: The millions to billions, was that--I didn't catch that. Was that government enforcement or industry implementation and enforcement?

MR. COSTIGAN: All the way across the board. You know, what you're looking at is the money spent by industry. Everything is being transferred further up to the suppliers, which is a good thing. You want to eliminate it at the source. So as a feed company says I'm no longer going to test my copper sulphate for this,

this, this and this, that becomes your responsibility. The ingredient supplier takes on that responsibility, passes that back to his supplier. Well, in the end, that supplier is up-charging more and it's passed through the system.

So no matter where the money is spent for additional inspection it will end up coming into the cost of the feed, into the cost of producing that animal, and into the cost of producing that food that goes onto the table. The consumer is the one that pays the bill in the end and the cost associated with that can be quite large.

QUESTION: Won't that cost ultimately be passed back to the producer because the price paid at the grocery store is based upon volume, not upon quality? So it impacts backward into the producer's hands. You're not going to get the consumer to pay more money for a commodity.

MR. COSTIGAN: And that's part of the problem. If costs go up how do you control those costs? When the cost of a program is introduced into your company you have to pay for that somehow. You either pay for it by passing it onto your customer or by reduced income. If

you reduce income too far those companies go out of business. If they go out of business, more demand, prices are going up.

Eventually it has to be passed back to the consumer. There's no way around it. There's not enough fat in the industry--no pun intended--there's not enough fat in the industry to be able to absorb a program of this size without noticeable effect to the consumer.

Anyone else?

QUESTION: I was in the first group and Tom talked about 25 to 30 cents a ton as far as the cost. Where that figure came from is that was a discussion within our group as to what companies, by and large feed companies, are paying today or it costs them today to do routine analysis of ingredients and finished products.

Now I'm sure like in your business with some of the assays you're doing that that cost may be a little low when you look at routine analysis, but as we talked about and as Tom related, as we talked about cost of implementing more specific programs, feed safety programs, we didn't settle on a final figure as to what that would cost but I think it's inherently believed that

there's going to be a lot of costs involved there to develop programs, train people, and get those implemented. But that's where that 25 to 30 cents came from.

MR. COSTIGAN: And when we were addressing the issue we were looking at it kind of broad-based and one of the things that came up was what's required to make the food source more safe? That's really the answer that we're trying to get to.

One of the things that was brought up was aflatoxin is a risk. So when I have to do testing, how do I control aflatoxin on corn coming into my facility? You know, there's factors that are outside of the farmer's control and there's factors certainly out of my control when I bring that into my plant, so I have to test every load of that. The cost of that test is \$6-7 per test.

Now another more recent issue that came up is dioxin. How do you know that it's in there, not in there, and what's the cost of that test? It's not \$6 or 7 a test; it's \$1,000 plus a test, so the impact of that is much great.

Now how do you sort out all the other issues that may come up that we don't know about? That's unsure but what we know is that to put a risk-based system in place, the majority of the companies have pieces of that; they do not have that whole system in place. To do that and do that formally is going to cost money and training with every organization all the way through, retraining of all the government inspections, kind of refitting them to do a different type of inspection, and then everyone looking at the way they do their job differently.

So the training costs there will be sizable and that's a big part of that, as well.

Any other questions? Thank you very much.

[Applause.]

MS. DUNNAVAN: Some excellent information for us.

Can I have group 3A, the spokesperson for 3A? Are you in the room? Can group 3A give us your discussion for question 4? Is that the one with the charts?

MS. COOK: That's the one with the charts.

MS. DUNNAVAN: I snuck into this room and saw the stuff they had on their wall. They had graphs and charts.

MS. COOK: As you can see, we had really good questions and as you can see, they did a nice job for us and put them all in the same place.

We had to address the identification and implementation of controls to effectively prevent identified risks. In 3A-4 they wanted to know how much was being done by the industry or how much we were seeing during inspections. They wanted us to give examples, so we'll look at that. They wanted to know if it was formal or informal. Would it involve training? It involves training to hold this up. And would it involve the purchase and use of new equipment and/or software; what kind? Unlike my predecessor there, it's going to cost us something.

Okay, for part A and the idea of controls, we decided that the industry must, as its first charge, maintain high standards to respond to competition and to reduce and eliminate liability concerns. These are largely formal instruments within the company. Most

folks have programs that have approved vendor lists, they have purchasing specifications, their own quality assurance program, whatever that might be, standard processing procedures for their operation, internal audits, finished product specifications, sampling and analysis of finished products at given times to confirm and assure product acceptability. They have customer audits and first, last, and foremost they have to respond to the needs of the customer.

The second part of this question had to do with would these examples here involve training and we said, of course, you have to train folks to do whatever it is that you need them to do, but the training needed to be attuned to the audience. If it's the farmer producer, he needs to know certain things that the transporter doesn't need to know, but the transporter needs to understand what he's dealing with so that he can handle it properly; the supplier has to know what happened with the transporter to make sure that he got the information that he needed; the manufacturer needs to know what the supplier did; the distributor needs to know what the manufacturer needs; the consumer wants to have all that

in a nice, neat package, but the enforcer has to know it all, too.

The key here is that you're looking at a one-up, one-back situation that we already deal with in most cases. Is it going to cost something? You bet. Is it going to take new equipment? Guaranteed. Is it going to take new software? Yep, that and personnel, too.

Now some folks say well, no, it's not going to bother our industry, but every time you add a layer of complexity to regulation or as a guideline, you have to look at new issues within your operation. We had a really good comment that if FDA supplied a program that was uniform for reporting purposes, just like they do for the Tennessee Valley Authority on fertilizer, that that would assist in industry communicating with the FDA. At that point then you have consistent software.

But right now the resources don't exist to do this at the state level, at the federal level or in the industry to perform something that's consistent with everybody else in the room. The industry, as I said before, has already dealt with most of these issues in-house and they have something that they're doing that

makes sure for them that they're not concerned about product liability.

I think we heard just a minute ago, too, that the consumer's going to pay. Well, it's the consumer at all levels. It's the consumer at the farmer level, it's the consumer at the processor level, and it's the consumer at the end point of distribution.

You know what? You didn't ask us a question where we had graphs. The next question was what kind of assurance would we need to establish or demonstrate that our program was functional? The first question was would we need a consultant to establish that. We said probably not but possibly so, that most folks understand where their critical control points are, even if they don't call them that. It's where the identification of risk takes place.

Would we need a third-party inspector to establish? Probably not but possibly so. A third-party inspection provides guidance that ought to let you know what is going on in your facility that you might have missed but in the case of a third-party inspection, the FDA should set the standards for that audit.

Would you need an on-going sampling program?

Well, yeah, you need to have samples to monitor products based on the risk. If you're, for instance, supplying a load of corn to a feed manufacturer, you'll probably want to have a sample of that to compare to his samples. If you're a farmer and your transporter's going to haul corn to your distributor or to your feed manufacturer, you'd certainly want to keep a sample of that so you knew that what he got to the plant was really what you sent.

We also thought that the on-going sampling program would give you an opportunity to look at the uniformity of the product that you were making.

And finally, I think--no, not quite finally--how would federal licensing and registration of all firms help? Well, there is an advantage to a uniform database. We found that out with the procedures around 589-2000 real quickly because we found that FDA had lists of companies that didn't exist anymore. We had companies who were processing with ruminant proteins that we weren't identifying when we initially started the program, so we found that there's a real advantage to having a uniform database.

However, you already have state licensing programs in place and the bioterrorism registration is going to come along and everybody in this room who deals with handling, storing, processing or otherwise is involved in food production is going to have to make sure that they're registered with our good friends at FDA.

Now should they share that information? You bet, because that's a one-time registration. However, we think that FDA has a problem because they're not given current information every year, so we think the state and federal groups need to work a lot more closely together to make sure that the information is current in all that database.

I think we have one more short page here. Are current enforcement tools adequate? They sure are, for the current product-based system, but they're probably not adequate for processing systems. The fundamental problem is that we are still a product-based country. Processing controls are not built into our regulatory programs and you'll be amazed to hear that I wasn't the one that said that. We did decide, though, that if you had mandatory controls at the product and voluntary

controls at the process that you would find that the current system of enforcement works.

Any questions?

MS. DUNNAVAN: Can I ask the member of 3A if they have any other comments they wanted to add?

QUESTION: Can I clarify something?

MS. DUNNAVAN: Sure.

QUESTION: You talked about the mandatory controls of the product. What did you mean by that?

MS. COOK: If you produce an adulterated product you already ought to be prosecuted. The law says your product will not be adulterated or misbranded, so the enforcement is in place to deal with that. There's nothing within a process control that says you cannot produce an adulterated product. If you have the wrong thing in at any step you could produce an adulterated product. That's why we deal with finished products here.

Any other questions? Any comments? Thank you.

MS. DUNNAVAN: And Nancy, would you just introduce yourself to everybody because we forgot to do that.

MS. COOK: I'm Nancy Cook with Pet Food Institute and formerly of the State of Virginia. Sometimes they like that; sometimes they don't. I like to prove that we have charts. We have decision trees and we have don't spend any more money on a safety or risk program than you can afford to get back from your product. So there you go.

MS. DUNNAVAN: Thank you very much, group 3A.

Can I hear from group 3B? B, will you do your answer for us for number 3?

MR. TSIEN: I'm Arthur Tsien. I practice food and drug law with Olson, Frank and Wheeda but I'm here with my AFIA hat on today.

Question 3, what are the benefits of having a federal animal feed safety system? The end goal, of course, is a safer animal feed and human food supply. In terms of how we get there, we think under a federal system we need to set and apply minimum standards to be applied uniformly across all segments of industry and by all segments, I mean commercial feed manufacturers, on-farm mixers, transporters, and so on. This will be to what we have often referred to as a level playing field.

A set of uniform standards should lead to increased consumer confidence. As part of this, it will be important to educate the industry and industry includes in this case producer groups. It will be important to educate regulators and this, in turn, will lead to an increased level of understanding of the requirements and what it takes to achieve a safer feed and food supply.

As part of this, the regulations currently in place should be reviewed and enhanced, where necessary. Hopefully this will lead to preventing future food and feed safety what we have called events, problems. And hopefully a uniform system will provide a better basis for foreign trade.

Questions, comments? Anybody from group 3B want to chime in?

QUESTION: Hi. This might be a question for Glo. In talking about creating a federal food safety program, where do you see the state programs fitting in? Do they go by the wayside? Are they there in addition to the federal program? What is the vision?

MS. DUNNAVAN: We would never, ever want the state programs to go by the wayside. You're never going to get Glo to say that. We rely very, very much on our state regulatory counterparts. We're in this together. So I think any kind of system that involves the federal has got to be in cooperation with our state counterparts.

How that would work I don't know yet and we would, of course, welcome any input from both industry and the states on how a cooperative program like that might work, but rest assured this isn't going to be something that FDA does hanging out there in the breeze by themselves. We cannot do our job without the support and cooperation of our state counterparts. It's crucial to what we are doing today and will be crucial to what we're doing in the future and we would welcome any comment on how that might best work.

QUESTION: Certainly I would expect that to be your answer and really, truly believe that that is what you mean and that we have a good relationship but we probably should consider the unexpected consequences. I look at USDA with the meat and poultry programs where there is a federal system and unfortunately, sometimes

states opt to get rid of their state program because there is a federal program.

So I'm not saying that will happen here but we need to be cognizant of that fact.

MS. DUNNAVAN: Absolutely point well taken. That is something I would hope would never, ever happen. Currently under the current system we are working now, we rely very heavily on that cooperation with the states and I just don't see that going away. That's a resource issue for both of us and it's really an overall consumer protection issue that you have both regulatory authorities on the same page working together, rather than tripping over each other or being counterproductive.

So that's a very good point and we need to make sure we keep that in mind in any future endeavors.

MR. TSIEN: Since I used very little time on question 3 let me segue into a related point, which my group discussed at some length. In my group there was general consensus between the industry people and the regulators that there are currently problems with unlicensed feedmills, especially on-farm mixers, and that

there needs to be a reevaluation of the current two-tiered GMPs.

Now FDA and state people working under contract to FDA have authority to go inspect on the farm. They may not do so very often but they have the authority under the federal Food, Drug and Cosmetic Act to do that.

The concern is that state people working under state law in some cases lack that authority and there was general consensus in our group that that authority needs to be added under state law so that regulators can get their arms around on-farm mixers. We think that's important part that would greatly enhance the current regulatory authorities.

Anything else? Thank you.

[Applause.]

MS. DUNNAVAN: Thank you very much, groups 3A and B. Very good information again for us.

[Whereupon, at 12:03 p.m., the meeting recessed for lunch.]

A F T E R N O O N S E S S I O N

[1:06 p.m.]

MS. DUNNAVAN: Let's get started. If I could have group 4A? I know that a spokesperson for 4A--are they in the room? They were in the room a moment ago. Okay. And 4A is going to answer question number 5, so introduce yourself, read the question.

DR. JOHNSON: As we go forward I'll thank Kerry as our recorder and I'd like to nominate our group as best group because we had good input, we had good facilitation, and no medical assistance was required at any point.

We were asked to answer number 5. You're leaving me? Okay, that's fine. There's one person in our group I want to take off of that, okay? We were asked to answer number 5 because we tried to tie number 5 back to 1, 2 and 4.

If we are thinking about a new animal feed safety system, if, we were not prepared as a group to assume the current one's broke. Can it be improved? Absolutely. Does it totally need to be disregarded? Absolutely not. So to assume that we're going to have a

new feed safety program is not necessarily something we were going to accept carte blanche, okay?

And there's a lot of things that went into that. Size matters. As we talk about a possible new system, is it going to be the same for everybody? Is it going to be the same for an on-farm producer or a multi-national? Is it going to be the same for a dairy producer as it is for a swine producer? So there's a lot of things in there that when we come to thinking about a possibility of a new system that we want to talk about.

Facility type we talked about. Public health impacts. As we talk about all the control steps--and our number 4 question was controls used to monitor the critical steps--when we look at the HACCP systems, the majority of those became not instantaneous but information that we could make on ingredient usage, et cetera, et cetera. But historical data is important when we start talking about pathogenic health and the human population and that was pointed out very eloquently in our group, that we don't want to forget the collection of historical data that we can use across the board and that

probably plays more importance into the food safety than it does in real-time animal feed safety.

We hear a lot about ISO-like programs. We hear a lot about HACCP-like programs. If you're going to spend the money to do an ISO-like program, do ISO. If you're going to spend the money to do a HACCP-like program, get HACCP-certified because it's a self-fulfilling death wish, in my opinion. You will have a problem. It will have a problem and you've got a problem because you were ISO-like; you weren't ISO. We're just asking for it from consumer confidence that if we are going to go down those types of roads we'd better be very comfortable that we can justify and that we can verify, that we can contribute the reasons to why we were ISO-like or HACCP-like and didn't go through with those types of verifications.

Since you asked, I'm going to give you our uniquenesses on the other questions. We wanted to get into some of the uniquenesses real quick when we talk about looking at other programs and if the possibility exists of creating a new one. Don't forget about international programs, particularly Canada. To ask multinational

companies, companies that have feedmills on one side of the border that go on the other side, or vice versa, to ask those companies to operate under two uniquely different systems is going to be tough. If we manufacture in the United States and have to go into Canada, that is going to be tough. If we manufacture under a certain system in Canada and can't bring into the United States, that's going to be tough.

Likewise, if we're trying to make a product for export, to put a system in place that's going to require a grossly different change to get a product that's acceptable for export out of the United States, that's going to be tough, as well, and unfair. So as you look at these different systems, don't forget about the international and the multinational usage across that one.

Components of a system, since you asked and I appreciate that--science-based, science of risk-based deal, flexibility. It's got to be a flexible program. Whether we want to talk about species or we want to talk about uniformity or whatever, it's going to have to have some flexibility in it. It's going to have to be

enforceable. It needs to be common sense-based. If we get too far out it may be there but it's not going to be used to the extent or bought into to the extent that we want it to. So it's got to be common sense.

It's got to be affordable. It's going to have to carry diversity, certification. It needs to be understandable at the simplest point. It needs to be tailorable or scaleable, depending on your size of operation, and it must have some plausible time implementation time line in it. You know, how long is it going to take to come up to speed?

We want guidelines for minimum entry and we'll talk about some of those real quick here. You know, what is the entry level? You can go past that but what is the minimum entry level? Is it species-specific? It's going to have to deal with education, it's going to have to deal with cost/benefit evaluation and certainly public awareness and outreach. So there's a lot of things in these programs that we have to consumer as we go on.

Minimum entry level. We would say things like some sort of drug inventory reconciliation. Now whether that's daily on a large commercial manufacturer or weekly

for an on-farm mixer who's using just premixes or something, some sort of drug reconciliation. Probably some sort of sampling on the finished feed, as well as in-coming ingredients and transportation-type sampling and that really is probably the minimum standard that would be feasible in any system, and we're almost there today. So the current system isn't necessarily broke.

There's a lot of other things we can do, whether it's labeling and tagging, formulation verification, sequencing, mixer validations--we talked about that as being a minimum standard. Ingredient tracking. If we went to total traceability and bar-coding, we have an extremely expensive implementation process ahead of us and then the billion dollar estimate gets to be somewhat real and for the smaller company or the smaller on-farm producer there are going to be some huge obstacles to that.

Employee training. We had a good discussion on employee training in terms of where do people fit in this thing? You know, how much money are you going to schedule or are you going to budget for employee training

and employee input? So we really want to be sure that the people get taken care of on this deal.

Formal versus informal training--I think that's going to depend upon the size. We don't expect to see a farmer-feeder ask his son to sign something that he was educated on how to feed those cattle. We're going to ask one of our mixers to sign something that he was educated but we're not going to expect a farmer-feeder to do that. So it needs to be really based on size, formal training, et cetera, and where it comes from.

Then 4D was in terms of--the purchase of new equipment or the use of new software, et cetera. Probably not in the minimum sense of the word. There probably should be entry level guidelines that you could get into this that wouldn't require a lot of financial capital outlay, all the way up to depending upon how big you are, how much you wanted to do this, you could spend just loads of money, but it is going to require extra personnel, particularly training. Can the FDA train them and educate them and everything else? That's going to be tough. And then sampling programs, test kits, et cetera.

Depending upon the guidelines, the cost of this is going to be unique.

We also talked quite a bit about the use of consultants. If consultants mean outside paid help, not necessarily. If consultants means continuing education, absolutely. You can go to the web and get information. You can do a lot of things but it doesn't necessarily have to require outside people to do that. Then third party, we always like third party.

Then think about sampling. We think finished feed sampling should probably be decreased, in-coming ingredients probably increased. We certainly want to talk about validation and verification and in particular, tie that back to exports.

That's pretty much it but again we're going to end on the fact that we're not necessarily ready to say the current system's broke but it can be improved. I guess that's a fair question that we really couldn't answer in our group. Has an animal feed safety system been mandated and is it a foregone conclusion that we're going to have one?

MS. DUNNAVAN: Do you want to introduce yourself?

DR. JOHNSON: I do not want to introduce myself. Kerry Krom of United Feeds and Bruce Johnson of Ridley.

MS. DUNNAVAN: Thank you very much, group 4A.
[Applause.]

MS. DUNNAVAN: Did anyone else in the group want to comment? Pretty comprehensive. Thank you.

I just want to comment that the question you asked at the very end, I've heard that many times during this meeting and I think as Dr. Sundlof said at the very beginning, we're looking for input from you. We're not at the point of mandating anything. We're talking right now about a system--what it would entail, what it would look like, what kind of information we need to hear from you.

So that's the kind of information that's important for us. Do you think it should be mandatory? Do you think it should be voluntary? Those are the kinds of things that we're seeking from you. So if you had that question and you have a burning thought on that

question and it didn't get conveyed today, please include that in written comments to us on your comment cards that are included in your packet. It's important information for us to hear and factor in in our future endeavor in this project.

Group 4B spokesperson? And let's hear question 3. And if you have any other comments your group wants to make, you can do that, also. Introduce yourself and read your question.

MR. WAWRZYNIAK: Hi. I'm Steve Wawrzyniak and earlier I heard everybody talk about how they got selected to be the reporter. I just thought we'd draw straws and as it turned out, I was the short straw.

On a serious note, as I looked at the last couple of days and I was talking to Glo earlier, I think we all could say thank you, Glo and George. You've brought a tremendous broad section of talent and disciplines from industry and academic, the regulators. I was also very pleased to see the CDC here and to hear some of their perspectives. So that was pretty significant and kind of neat how you brought that together.

So I've been asked to give the input that our group had on number 3. What are the benefits of having a federal animal feed safety system? And number 5, in conclusion, are there any additional thoughts or comments this group would like to convey to FDA regarding an animal feeding system?

Well, since I was the short straw, I'm going to give you my Polish interpretation of my notes here. So the benefits, and I've kind of combined both questions if you bear with me, what I did is I just took sound bites, if you would, some comments that were made and kind of combined them in kind of a unique order.

Some comments were the benefit is it'll provide uniform and consistency but it has to be flexible. Enforcement has to be consistent and firm but enforcement has to be understanding and we need exemptions.

The bad guys, they should get the hammer but the good guys, we'll get the hammer, too.

Federal programs would have to be broad and they would have more consistent programs and more power. But what about the federal programs and the impact they would

have on states' rights and the fact that they may ignore some of those states' rights?

It would save money; it would cost millions. Some companies already have and comply with most of the programs. We have SOPs and HACCP and ISO. Some companies don't have anything to comply with.

Feed safety system training is very critical and significant, more significant and beneficial than just maybe the regulation itself. It will mean everything would have to be documented. Not everything has to be documented, does it?

We need to have farm mixers consistently inspected and regulated or the program, that means that'll happen. FDA has the authority but not the resources. It's not a regulatory priority and may not even be politically advisable.

Federal regulations need to be doable. We do not want to set up people for noncompliance. We need not to be overcautious and not be in denial of a feed safety system. We also need to be cautious about overexpectations of the benefits of a feed safety system. That's it.

[Applause.]

MS. DUNNAVAN: Okay, you're not going to get away quite that easily.

I want to make sure first if anybody from group 4A or 4B has anything they want to add to your spokesperson's comments. And are there any questions from the audience for group 4A or 4B? Here's a question in the back.

QUESTION: For 4A, you talked about the system working pretty well and that it could obviously use some tune-ups. My question basically relates to your group and maybe some of the other groups would want to comment, as well.

Was there any particular area that you saw that the consumer today is at risk due to our feed safety systems that are in place already?

DR. JOHNSON: Excellent question. We tried to-- and I'll ask the group to help me on this a little bit-- we tried to think about this it relates to animal feed and food safety. Safety risks within animal feeds kind of have a way of self-regulating themselves. If it's

toxic to the animal, the animal doesn't go very far, so it kind of is a self-regulating situation.

Within our particular group we got into the discussion more as it relates to pathogens and I think somebody talked about you can take sterile feed out of the feedmill but it's going to be recontaminated, and the pathogen flow, and that's where the comments from the CDC came in in terms of historical data does have significant benefit.

Probably where we've found the weaknesses in the current system is probably employee training and employee empowerment. You know, who in your system can say stop, this isn't what it needs to be?

Group, help me out here. They all left the room like the last time. Jim?

PARTICIPANT: The on-farm mixer-feeder is the weakest link because it's the least regulated and the most likely to cause a problem from poor education or employees or whatever.

DR. JOHNSON: Did that answer you adequately or you want more? Great.

QUESTION: If I could just add something? I think what you said is correct and it was a wonderful question. Is the system adequate for our current needs? Most likely, yes. Anything can be improved. But I think at the beginning of the meeting we talked a little bit about bioterrorism. Should we just be thinking in terms of our current needs or what happens if there is a bioterrorist attack? Will our system meet those needs? That's perhaps what we should explore a little bit.

DR. JOHNSON: That's a good point. I like that thought. We did not talk about that but in terms of disaster recovery or something like that, that might be something a system could address as such--you know, what's minimum? Minimum record-keeping, things of that nature. We didn't go down that road. But current ISO systems, current HACCP systems, et cetera, do cover a lot of that in terms of policies and procedures. Good point. I thought I got out of here.

QUESTION: One of the things that we talked about in our group as far as a weak link was past the actual manufacturing at the grower, if you will, or the dairy and that's culled cattle and it's the truckers--

haulers after that point. When you have a culled dairy cow that you've shot up with umpteen doses of penicillin and just enough that it can walk, that's where we thought the weak part is as far as the human food supply, or one of them.

DR. JOHNSON: I agree. That wouldn't necessarily be addressed in an animal feed safety system.

QUESTION: Why?

DR. JOHNSON: Why? Why not? We're talking about injectables versus feed.

QUESTION: It still could be the medicated feed, too. I mean a lot of--

DR. JOHNSON: It could be. That's exactly right, on withdrawal. Current system--is that a question of an inadequacy of the current system or is that a question of enforceability of the current system?

QUESTION: Good point.

DR. JOHNSON: Fair enough.

MS. DUNNAVAN: Thank you all very much. Very good discussion. Thank you, groups 4A and 4B.

Let's hear from 6A. Do we have a spokesperson for 6? Let's do question 4. Just introduce yourself for the record.

MS. BARRELL: I was going to say I was probably the short straw. I'm Regina Barrell. I'm with the FDA Denver District and I was going to say I have a pin that says "I'm from the government; I'm here to help you" but I figure all of you wouldn't quite get that joke.

Our group, question 4A, had to deal with recordkeeping and system validation. We discussed it as far as--there was a little confusion because we weren't totally clear on whether we wanted recordkeeping as one subject and then validation of systems as another, but we decided the question dealt all with recordkeeping. So we attacked this looking at it from the types of records that need to be kept and the training that needs to go along with it.

4A was how much of this are you doing as a firm right now or how much of this are you seeing during inspections of feed and feed ingredient manufacturers? So what we did was just list some of the knowns that we have out there as far as what people are doing.

Obviously the first one that came to mind was the GMPs. General business, and by that we mean general business records, that would include invoices, that type of buying and selling invoices. Quality of records that might be kept as far as analytical records or some of the other types of records such as in-coming inspection records that would be done. HACCP plans, ISO training records, SOPs, MSDS sheets, analytical records, and then transportation records.

So these were pretty much what we had thought of as far as what recordkeeping that firms are normally keeping and the type of things that most businesses, depending upon the scale of the business, would have some of this. Obviously not all of them would be found in, say, a small farm operation but I think most large businesses would have quite a few of those.

4B asks as far as recordkeeping, are there formal written policies and procedures or informal? Again our group recognized that because you have such a wide variety of businesses it can run the gamut. Basically if you're a large operation we would expect to see formal written procedures and have written policies

but if you're a small farm operation it may be word of mouth. And I think other groups had touched on this as far as it may be a family-run business, that you wouldn't expect to see as many written policies and procedures.

So it varies a lot by the segment and that was, I think, the biggest thing that came out of our group, was that to have any kind of regulations that encompass all types of industry and all sizes is going to be difficult.

Okay, this question was would this involve training? What kind of training would be best for this and how often? This was a fairly good discussion because even though all it says here is yes, obviously we figure that there will be training necessary, but we tried to think of the best way to go about training people in recordkeeping. Again the same thing comes back--various segments at various levels. Some industries, some businesses are at a very high level and there wouldn't be a lot of training necessary to teach what type of records need to be kept and how to do them. Obviously some firms are not at that level.

We did agree that a joint educational program would be the best way to do this, to have an FDA industry state-wide training where everybody hears the same thing at the same time. So we were looking for a standardized type of training where hopefully everybody hears the message together and the understanding is done at that level.

Obviously if you have new employees or new responsibilities we would expect training to occur. We need to have the process, including the reasons, and by this what was stated is people usually follow things if they understand why they're doing it. If it's just a blanket thing that you need to keep records and they fill in the blanks and have a stack of records, the person doesn't quite understand why that record is important to keep. So we want to emphasize that the whole issue here is food safety and the fact that you need to keep these records is to ensure the safety of that product once it's out the door and beyond your control--not beyond your control but once it leaves your premises.

There was also a big consensus that inspectors need to be trained and need to know the operations of the

types of facilities that they're going to be inspecting. Again this kind of goes back to this joint educational process where we have a group consisting of both industry and regulators.

Consistency? Obviously the training should be consistent so that everybody hears the same thing, uniform interpretation and identification of key elements, again going back to the fact that not everybody's the same and you have various types of producers, everything from medicated feedmills down to on-the-farm blending operations. There should be key elements that are common to all of them and obviously some elements aren't necessary to be kept but other ones we figure should be kept by everybody.

4D. The next three questions we got kind of lost because it all depended upon what your situation was in the first two. Would this involve the purchase and use of new equipment and/or software? Obviously it depends on your operations. If you've got a very complex industry or you've got a complex facility that does a lot of different things, you've got computerized equipment and processes, obviously you may need to buy computer

equipment and have software that keeps track of things. If you're a small operation, probably not. So recordkeeping can be anything from a pencil and paper up to a large computer system.

4E, what kind of cost do you think this would entail? Again it kind of goes along with the first question. It depends on what we're looking at. If you're an operation that's complex and maybe you're not computerized, it'll cost a lot to get you to the point that you need to be at but if you don't need to keep that, if you're a small operator, independent operator, perhaps the cost wouldn't be that great. We have the same answer every question--it depends on the firm.

What kind of assurances would you need to establish to demonstrate this is functional? Would you need a consultant to help you establish this? Would you need a third-party inspection to establish assurance? And how would federal licensing and registration of all firms help?

This one we really kind of fell apart in finding an answer for because again there's such a wide variety. I think this is true for a lot of the different aspects

that everybody talked about but depending upon what your needs are and what your processes are, it would depend. We really didn't get into a big discussion of that one.

And I guess 4G, how do you envision risk, both animal and human health, being introduced into AFSS? Should the risks be identified by industry or government or both?

In this case we felt the answer to both of these questions is that both the federal, state and industry need to identify the risks. We don't believe one can identify the risks alone, and we actually think that it should be done jointly, together.

And the last one, are the current enforcement tools adequate? This, I think the last group mentioned. Enforcement tools need to be applied to all segments to ensure the food feed safety on a risk assessment basis and that was a very important thing, that we wanted everything to be science risk-based, that there's grounding for it and obviously apply it across the board so one industry wouldn't be singled out or one size industry wouldn't be singled out.

So I think that was it.

MS. DUNNAVAN: Does anybody else from group 6A want to add anything? Does anybody have any questions for 6A?

[Applause.]

MS. DUNNAVAN: Thank you, Regina.

Let's hear from group 6B. Spokesperson here? Introduce yourself and just do question 4.

MR. ARENTSON: Hi. My name's Bruce Arentson with Kent Feeds located in Muscatine, Iowa.

We're dealing with question 4, with recordkeeping and validation of the system. As we started thinking about validation we had two different interpretations of what validation is. We had one side said well, validation is making sure the system works before you start doing the system or performing the system. The other side says well, it's kind of the sixth step of the HACCP program.

So we just ended up saying it kind of includes everything from monitoring to making sure the system works and tried to put that into our answers to these questions. So we've answered number 4 with recordkeeping and validation.

How much are you seeing during the inspections? Well, we don't have a lot to add to this. The medicated feed manufacturers have a very significant amount of documentation and recordkeeping that includes the prohibited material and nonprohibited protein records, transportation records, good manufacturing records, and also they would have just regular accounting and tax records.

But we also have to give the livestock producers credit, too, because we looked at this from the eyes of that we would have this feed safety system throughout all the industries, including the producer, the small on-farm mixer to the large on-farm mixer to the crossroad mills to the large feed manufacturer multi-plant manufacturer and a lot of these livestock producers do have a significant amount of records, feed records that they have documenting what medications they're using, what sorts of products, ingredients they're using in these products, and the actual amount of feed that's used. I think that's true for the pork, beef and poultry industries.

As far as how many are you seeing in validation? Well, that depends. It's just everybody uses validation or has some sort of validation down to nothing as far as validation.

Compliance issue. 6B. Is it formal or written policy and procedures? Again it's all over. It's both formal; it's also informal and it depends a lot on the firm size and/or corporate oversight. A lot of the multi-plant corporations do have people who are specifically in charge of the recordkeeping and validation procedures.

So we go on to would this involve training? As far as recordkeeping is involved, yes. It's a simple answer. What kind would be best? Well, we have on-the-job training, we have position standard operating procedure training defining exactly what that position does. We have quality control, quality assurance training, written recordkeeping training procedures, management training.

So if we have a new system, a feed safety system, there's going to have to be a training mechanism set up to train the management people to train the

others, the actual workers in the plant, and that could involve on-line or CD-ROM material, it can involve university extension services--I think that's been mentioned earlier. Producer groups--the National Pork Producers, National Cattlemen's Association could be involved.

Then as far as recordkeeping, the group thought that maybe FDA could have templates of the records that would be needed by all different aspects of the industry.

And there was some thought that if we're going to do the system, and this is just a thought that was thrown out, that it could follow something similar to the plant pesticide licensing that is involved in using the pesticides that are out there. So that could be one type of training mechanism. But again it all depends on what we're going to use in the system and risk assessment and that risk assessment, from what I understand, is still a black box. What is risk in this type of operation may not necessarily be a risk in another aspect of the industry.

And the training is going to be continuous, especially as you have new employees, and so on. And

again the training's going to depend on the risk assessment.

D, the purchase of new equipment--maybe. If the FDA is going to have oversight of the whole feed safety then there's going to be a tremendous amount of resources involved--of people, cars, computers and training, contract costs if they contract with the state departments of ag to do that, down to maybe just some new equipment, depending on what type of program is set up.

What kind of costs would be involved? Again if there's a third-party certification process set up somebody's going to have to pay for that third party to provide the training to the different parts of the industry--the transporters, the producers, the cross-road mill people, and so on. If the government is going to do it, provide oversight, enforcement, there would be increased personnel, again possibly computers and equipment. And, of course, there's going to be industry training costs that will be involved in this.

F, what kind of assurances would you need to establish or demonstrate this is functional? Would you need a consultant to help you establish this? Again we

ended up saying it depends on the risk assessment, that kind of black box--what is risk assessment? It's going to be different probably for all different parts of the industry. So the questions for F, I think we ended up saying it depends on risk assessment, depends on risk assessment, on-going sampling. That question was in there and yes, but sampling will depend on risk assessment.

Federal licensing--how would federal licensing/registration of all firms help? I guess we have major firms, yes. Major firms would be required probably to be licensed, as they are now. Then who else would be required to be licensed? That would be a good question. It would probably depend on risk assessment.

How do you envision risk assessment being introduced into the animal feed safety system? Identify by industry or government or both. As previous people said, both involved in this and probably other government agencies would be involved, such as CDC, USDA, EPA, FDA, and Homeland Security.

Are current enforcement tools adequate? We had quite a discussion on this and we were pretty heavy in

the regulatory people who are involved in this and basically they said no, but it depends. It depends on how much the state partners are involved. Their concern is at the federal level things don't always move quickly enough but if there's a state involved where they can partner in enforcement, then it can move a little quickly because the federal do not have stop-sale authority.

Oh, and then there was one other comment. If we had a good program, why would we need the state counterpart to be involved in feed safety? But of course we'd probably need them. I think the group said that--

QUESTION: That was Oregon, by the way?

MR. ARENTSON: But, of course, they would be needed for enforcement.

So that pretty much answers our question on 4. Any questions?

[Applause.]

MS. DUNNAVAN: Thank you very much.

Just a little housekeeping. For all of you, your flip-charts, we want to keep those flip-charts. Make sure you leave those with the scribe. If you were a scribe for a group, make sure you walk out of here with

the flip-charts for your individual group because we do want to keep those and review the information that you've put on the flip-charts.

Let's hear from group 2A. I know you think I forgot you because we've gone past you. Do we have a spokesperson for 2A? Great. Introduce yourself.

MR. O'HARA: My name is Richard O'Hara and I come from Farmers Cooperative here in Frederick, Maryland, just about an hour and a half north of here, and we're doing 2 and 4.

Question 2 was what do you think are the basic elements of an animal feed safety system, remembering that this is or will be for all feed and feed ingredients, commercial manufacturers, distributors and on-farm mixers?

We spent probably the most time on this one question and we went down through the question and, as was mentioned earlier, came to the conclusion that the HACCP approach really covered everything pretty well and fully agreed with the seven elements in that. We even went down to the point of what the different items were, broke it down into chemical, physical, biological and

TSEs and which of those carries from the animal to human consumption.

But in the end, after all of that, we came up with three easy key elements to an animal feed safety system and that was to make it easily understood, easily measured, and easily enforced. So half an hour's talking into three lines. But like I said, we broke it down between animal and human, made it chemical, physical, biological and TSEs and then what would transfer over, but in order to have an effective system or basic elements--and it's asking for the word basic--easily understood, easily measured, and easily enforced.

Then for question number 4 our specific domain for question number 4 was the identification of risks associated with the process and the product. So for question A, how much of this are you doing as a firm right now and how much are you seeing during inspections of feed and feed ingredient manufacturers and distributors, and give some examples.

We listed down through point of sale, certificates of sale, records kept for drug administration, ingredient records, written

specifications, supplier credentials, sampling, testing, and written plant procedures, and this was throughout the entire group. Our group was about split in half between industry and regulatory.

As far as B went, we kind of fit A through E all into one lot. For B it was both. In our group we had both people who were working on a formal level with written specifications, with written letters, as well as those who are on a nonformal level or an informal level.

As far as new equipment, we were looking at this from the standpoint of the firms that were in our room and no new equipment was necessary; this is already taking place.

As far as increased cost, there was no additional cost necessary because these things were already taking place.

And training was going to be necessary but for those who already have this installed there was no new training necessary there. One member of our group did mention that there was training biannually and for new employees if I remember correctly, and this is something

that we talked about but as we say, if it's something previously installed, then nothing new is required.

What kind of assurances, for question number F, would we need to establish or demonstrate that this would be functional? We came up with testing, recordkeeping, measurements, internal and external audits, and occurrence outcome solutions.

Again we kind of meshed F, G, and H together there as far as our vision of risk. We put it as a science-based risk assessment and definitely not limiting it to a precautionary principle. We listed out some of our ideas of risk, which were human illness and human death, animal illness, animal death, economic impact and animal performance levels.

And the answer to question number H was--the question was are current enforcement tools adequate? And we said no originally and changed that to a yes with a subthought to number 5. That was that the tools are adequate but the enforcement with the authority in some states is not. Some states do not have the authority to pursue enforcement where some states do. So it's not even across the board. Also, with the idea that industry

should be a primary driver in this compliance with the government, and that went back to our three steps in the beginning--easily understood, easily measured, and easily enforced.

Any questions?

QUESTION: Did you say that you supported a precautionary or you were opposed to a precautionary approach?

MR. O'HARA: Opposed to precautionary only.

QUESTION: What was your point on animal performance?

MR. O'HARA: That was as a risk assessment, what was our definition of risk, and that was one of those-- the risk of animal performance in regards also to human health and human illness, animal death, animal illness, economic impact and the animal performance itself. An animal doesn't have to be ill to not produce milk or to not lay eggs as efficiently as it could otherwise. That was our assessment of risk, some of our definitions of risk.

Any other questions? Thank you.

[Applause.]

MS. DUNNAVAN: Thank you very much.

Can I just ask the last questioner, you have a very puzzled look on your face. Do you have a follow-up question for that?

QUESTION: Maybe just a follow-up comment. I think 2B took a different position on economic performance versus food and feed safety. We thought they were quite different, so we discussed that and put that out as not being part of a system.

MS. DUNNAVAN: Are you the spokesperson for 2B?

QUESTION: No.

MS. DUNNAVAN: Okay, thank you very much. Any other comments from the rest of the group?

Okay, how about 2B? Be sure and introduce yourself and you're going to do 3 and 4.

MR. JONES: Hang in there, guys. It's almost break time. My name is Ben Jones and I'm with the Office of the Texas State Chemist and was the lucky one to become the spokesperson for 2B.

We have been asked to look at questions 3 and 4. We had a fairly vocal group once we got going. I want

you to know that all of the opinions I'm about to express are not necessarily my own.

Number 3 asks what are the benefits of having a federal animal feed safety system? We took a two-pronged approach to this. We did list some benefits and I'll talk about those momentarily, but we also listed some disadvantages that we thought might be associated with it and rather than put that into number 3, we rolled it down into number 5 but I think it's important that I stress those, as well.

We'll start with the benefits. Uniformity, which has already been mentioned here, uniformity of the system across the states and the nation certainly was one. A national perspective versus a local perspective with regard to animal feed safety and the resulting human food safety. It was felt that it might be potentially a better funded project if it was done at the federal level versus state level, since so many of the states have been having budgetary problems in the last few years. It might be more specific to task. There could be some increasing consumer confidence that resulted out of a

federal system, not only domestically but potentially in global trading, as well.

The potential for it to be more consistently enforced was mentioned. That consistency and uniformity is, of course, an underlying theme here that kept showing up, as well as this next one, the level playing field, which has already been mentioned by a number of people answering this question.

Again it could help trade. We would hope that it would harmonize with some other government regulations that are already in place. Again we would hope that it would be risk-based but we felt like it would require more science to quantify the risk than we have at this time.

It should reduce the number of variations that are in current regulations. We would hope for consistency and clarification, more consistency and clarification. We hope that this system would reduce any nonrisk-based regulations. Tim mentioned that earlier. We did have a fairly lengthy discussion about animal feed safety, human food safety issues versus what we've

historically looked at as economic fraud or economic issues.

And finally, I believe our bullet point of prioritization of resources was mentioned, to look at what would be most significant for the safety of feeds resulting toward the animal and humans and being able to put the resources that you have at the top of that list.

Can you go back to 5? I don't think I have that in my notes. By the way, this is Chaundra Hardwick from the Department of Agriculture in Colorado who's helping me today.

Some of the negatives that the group discussed were that it might be a much slower and long time to enact this regulation, to get it into place and running, than the current state system and what we have now. Another negative, that the economic impact on small mills and on-farm producers would be dangerous, putting them out of business. I think Constantine's already alluded to what happened with the USDA meatpackers when they went to HACCP.

Another possible negative is the loss of state programs, again which Constantine talked about earlier.

Then finally--is it finally?--oh, we've got pages and pages of negatives. Enforcement resources. Where's the money going to come from?

Difficulty to achieve uniformity on the national level. It's already extremely difficult among the 50 states and we feel like a federal program would still be difficult to achieve uniformity across from ocean to ocean.

Difficulty to get full state representation in this program. The impact that it might have on other regulations and agencies. Few of the risks actually have been quantified and are science-based. And imports and possible unfair competitive advantage in the global market trading. That would be number 3.

What else did you give me? 4? That's that long one, isn't it? My group was looking at this from the aspect of the identification of risks that are associated with process and the product. We're going to try to answer A through H right now within 10 minutes.

How much of this are you doing as a firm right now or how much of this are you seeing doing inspections

of feed and feed ingredient manufacturers and distributors? Give some examples.

Varying opinions, of course, among the group because we had industry, as well as regulators there. There were comments made that almost all are doing some assessment of risk within industry today.

Oh, let me explain to you. The black words and phrases are comments from industry; the green are government comments. One of the government comments was that many mills do not have any risk-based systems. Typically that's the smaller firms and various sections in the manufacturing industry and that is putting it lightly.

Another comment from industry--audit dealer and copacker. Okay, they wanted to see--help me with that, Tim.

PARTICIPANT: Some companies are auditing their copackers.

MR. JONES: Whether they're multinationals or not, they have not only their internal audits but they go out and audit, of course, the ingredient suppliers and dealers and copackers for the firms.

Help with quality programs. For example, one representative within our group had done nine audits on these copackers and firms in the past month and again internal audits, as I mentioned before.

Another response from the government--once the problem has been identified, resources are devoted to follow up on the problem--seizures, stop-sales. Wow, I think I said that.

Somebody asked me, you know, how do we prioritize who we're calling on, where we're going to spend our resources? My example, of course, if we find a problem, if we uncover a problem and if it's a significant health of animals or human issue, then we're going to put that as our top priority within our agency.

Another industry comment--periodic testing if risk is present and implement on-site testing.

Another government comment--has seen traceability increase in the industry. The comment there was that it was a positive comment toward industry, that there's been an increase in the past few years of lot numbering and production date coding to help with the traceability and recall efforts of the firm. And one of

the great outcomes of that is if you have that ability within your company then you don't have to rely on our recall procedures, which are usually more costly to you and a little more widespread.

Finally on this question industry stated that the traceability and cost-effectiveness was the key to risk management.

All right, B. Is it formal written policies and procedures or is it informal? I guess the consensus of the group is that there was a little bit of all of that within the industry, you know, looking from on-farm feed mixers and single ingredient suppliers to multinational companies. We see a little bit of all of that.

Government stated that some firms have written policies, some don't. Again an industry comment--out of those nine audits that were performed in a month's time only two had written procedures in place.

For the small producers, recordkeeping will be a burden. Some will go out of business. And recommend review of effects from meat plant regulations and how it affected the smaller firms, as I talked about earlier.

C, we have the question: would this involve training? What kind of training would be best for this and how often? Consider this answer for both industry and government.

The government said shift training from just compliance to philosophy in answering the question why. In other words, what happened here is it's difficult to get someone to buy in and try to proceed through a system like this just because you're coming in there with that big stick and ramming it down their throats and telling them it's the law; you've got to do it. You need to have some mechanism to show them philosophy of why it's being done and the benefits that could be associated with it.

Training. Now in the food business, similar to something like HACCP, CODEX and the seven principles--I guess that's of HACCP. But I think the gist there was we're not raising cattle anymore, we're raising food, and you need to be aware of that from the farm up.

Another government comment--some farms will have to have training mandated to them, have to implement the program by a certain date. In other words, there has to be a target date there or you won't get the people that

need the training trained in a timely manner for implementation.

D, would this involve the purchase of new equipment and/or software? We're still on C? Okay.

There is a varying level of education out there when you go to train people and the comments were made that you might be dealing with someone that hasn't even completed high school up to Ph.Ds. in various subjects and that it's hard to put together a training curriculum or coursework that is going to be tailored to that widespread range of persons.

Train the trainer was mentioned, of course. Follow with tests, open book, know where to find info. Boy, I must have been sleeping right there. Anybody from the group have a comment on that?

PARTICIPANT: Mike's comment was they want people to know where to find the information, to now always have instant recall. I think he also said they do test and if they fail the test they don't do the job.

MR. JONES: A government comment. Firms need incentive to show up for training.

D, would it involve purchase of new equipment and/or software? We felt like in general there probably would be some software, additional software that may be required. It would probably have to be custom-designed. No one really knew of anything that was off the shelf or ISO or HACCP, so it could be expensive because it needs to be custom-designed.

Government stated that equipment may be needed, some additional analytical lab equipment, et cetera. That's about all we had on that.

On E, what kind of costs do you think this would entail? The cost to bring a facility up to a point for HACCP, I don't know. I don't remember Mike's comments on that or any other industry comments. I think in general we thought there would be some costs involved there but we certainly didn't look at any dollar figures. And, of course, government didn't have a clue so there wasn't a comment on there at all.

What kind of costs do you think this would entail? We thought there might be some costs in there for third-party audits. That's really all that spun out of that. Oh, and the government said there would be

potentially some political costs, maybe not monetary but it could certainly strain some of the political arenas and get some controversies going amongst some of the politicians.

The cost of doing things right? What does that say? Contaminating ingredients.

F, what kind of assurances would you need to establish or demonstrate this is functional? Would you need a consultant to help you establish this? Would you need third-party inspection? Would you need on-going sampling? And how would federal licensing and registration of all these firms help?

Multiple forms of assurances based on company. I shouldn't have lost those glasses in Denver. Internal and third-party. Government statement, prioritization of sampling programs based on feed and safety. That's where we got into the discussion about safety versus economic. And reward for companies with internal and external audits, get less inspection. That was again a prioritization of the government resources toward these firms. In other words, if you had all these things in place and they were verified, that there would be some

lessening of frequency of inspection and more emphasis could be placed on the firms that did not have programs such as this in place or weaknesses that were known.

Standardization of sampling was mentioned across the board, I might add. It was mentioned for on-farm mixers on through the nationals. And protocols were mentioned.

How am I doing? I'm out of time? You want me to stop?

G, how do you envision risk for both human and animal health being introduced into the animal feed safety system and should the risk be identified by industry or government or both?

Risk should be identified by both government and industry. They ought to be partners in this effort. There ought to be objectivity within the Food and Drug Administration during this effort.

H, are current enforcement tools adequate? We thought they were adequate for the BSE regulations. The others, we do not think they're adequate, dependent on politics within the state and the comment was made that we needed more documentation and clarification--letters,

et cetera--for support with problem firms and getting into these court cases.

Okay, real quick, this was an underlying theme of the group, that the FDA must foster a cooperative environment with industry and the states in developing this system, that past experiences have shown participation and sharing from the industry with FDA has not produced the expected outcome. And there continues to be a lack of trust and confidence between the FDA, industry and the states and we hope that we can take this opportunity to get all three of these parties involved in the development of the annual feed safety system from the get-go. Thank you.

[Applause.]

MS. DUNNAVAN: Thank you. We're really running short on our time. That's okay, Ben. That was a very good discussion, but I do want to give groups 5A and B an opportunity to report on some of their discussion.

So could the spokesperson for 5A come up? And Randy, introduce yourself and can you do 4?

MR. GORDON: I'm Randy Gordon with the National Grain and Feed Association and Glo, I tried to help you

out on your time situation but Ben wouldn't take my call. He rarely does.

Well, thanks very much. And I wanted, before I start, to give Steve Wawrzyniak one comment. You know, he talked about being the short straw. The first speech I ever heard Robert Reich give, who was the labor secretary under President Clinton and who Steve towers over by at least a foot, was, "I bring new meaning to the term 'big government.'" So we're hoping this doesn't evolve into that.

Well, I think maybe as a preface to question 4, our group talked quite a bit about the basic elements of an animal feed safety system and I just want to touch on a couple of predicates or prefaces on that.

We really felt that it obviously needs to be a science-based system that needs to be formalized through a risk assessment process and I think we'd reiterate the comments made earlier by other groups that that may take quite a bit of research to develop the scientific underpinnings for what the hazards are, at what levels are they hazards, and also to develop the kinds of diagnostic tests and quick tests that industry sectors

may need to monitor those hazards in your plants. Tests need to be affordable, repeatable in their results and consistent in their results and also be very quick, as well.

We think it should be a comprehensive system that looks at all sectors and we focussed quite a bit on the transportation sector, too, and the fact--that we didn't mention this specifically I our break-out group, but the Safe Food Transportation Act that was passed back in 1990 requires haulers, both independent truckers and rail carriers and others, to provide clean and safe equipment to transport food products, yet those standards have not yet been developed here 13 years after that act was passed. So that's a classic case of looking at the transport side a little bit.

We talked about the flexibility to accommodate the variations of different risks and hazards that may be identified in different industries and that guidance and education may be the most appropriate means to identify and communicate specific risks and hazards to various industry sectors. We talked about looking at some of the documents that AFCD has developed, the guidance framework

document and some of the checklists, and so forth developed through that entity as a possibility, and also the voluntary self-inspection program concept, too, that Ben alluded to that provides regulatory incentive for companies to implement quality assurance programs by placing them at a lower priority for inspections and oversight in the future.

We also talked about the importance of differentiating or considering facility security differently than feed safety systems. I mean we're mixing the bioterrorism and some of that into this issue but they are not synonymous and the facility security-type issues should not overwhelm the animal feed safety system initiative, although we think it's important that we do need to evaluate which animal diseases are at risk of being transmitted through feed or feed ingredients as a component of security. So that's an important caveat to mention there.

Okay, in terms of question 4, with that background, we were asked to focus on the issue of assurances of what steps are being taken to ensure that animal feed safety system steps are being accurately and

consistently performed. And in terms of those assurances, we focussed quite a bit of discussion on the recordkeeping and documentation that might be needed, also the sampling and the periodic assays that might be required, as well as the education and training components and the diagnostic tests that would need to be available, particularly for the sampling components.

We were asked this question, of how much of this are firms doing right now or how much of this are you seeing done through inspections. Again we reiterate what a lot of the other groups have said, that it really depends on the size and type of firm. For the medicated feed industry that's been used to complying with GMPs for many, many years, you'll tend to find those kinds of records and systems in place. As well as some of the quality systems we heard about yesterday where companies for customer-based reasons have developed and implemented their own quality assurance programs you'll find pretty good records and recordkeeping and documentation there, that their systems are being adhered to and verified by their employees.

Are these formal written policies or procedures or informal? Again we reiterate the comments of other groups that it really depends on the company, the kind of industry sector you're dealing with, whether they have a history of being regulated under FDA, like the medicated feed industry, or whether they're not, so it really varies.

And it's not necessarily the size of the firm, either. You can find some very good records and documentation in small firms, as well as large, although in the smaller firms you tend to find it fewer times because they do tend to operate more word-of-mouth and there are two or three people there that know the procedures inside out in some cases, although that's not always the case and in some cases there are not good procedures in place for recordkeeping or documentation.

Would training be involved? Yes, it obviously would for both industry and inspectors, to increase their understanding of what kinds of records and sampling procedures, and so forth are necessary.

D, would this involve the purchase and use of new equipment or software? It might, depending on the

degree of automation, particularly in recordkeeping and documentation that companies want to achieve, but in many cases smaller companies in particular rely on manual records to comply with whatever hazards are identified through this animal feed safety system initiative.

Question E, what kind of costs would this entail, we got into some discussion of this but not a lot. It could involve the purchase and use of some equipment--software for the kinds of recordkeeping we're talking about, and also for sampling and testing for different kind of hazards, but until we know what those hazards are, that's really kind of a difficult question to answer at this stage.

F, what kind of assurances would you need to establish or demonstrate the program is functional, we really didn't focus an awful lot on that topic, although we did talk some about what kind of verification and documentation might be required.

But those are kind of an overview. I've tried to eliminate some of the redundancy that we had with some of the other groups but those are some of the highlights that we had in our group. Thanks.

[Applause.]

MS. DUNNAVAN: Thank you, Randy, very much.

Let's have the spokesperson for 5B. What I'd like to do is ask you to--I haven't asked anyone to address question 1 so I'd like you to address question 1. Then also if you have anything that you'd like to add additionally to question 4? Be sure and introduce yourself; read your question?

MR. BROYLES: This is Brenda Ball. She took all the good notes. If I took them you wouldn't be able to read them. Our FDA person's not going to come, I guess. Everyone's still here. We thought everyone would be gone by now.

Question 1, I think these are really available on most web sites. They're easy to get to for these associations and I think this is pretty commonly given information, really. If anyone wants to see this we have it up here. If anyone wants to see this we'll have it available whenever you want it.

Is that enough for 1? There's a lot of redundancy.

I thought we had a very good group. We had FDA people, state people, we had industry people. The frightening thing is I think we agreed on almost everything.

On question 2 we broke this out into various sectors. We have transportation on top and Randy had already pointed out the 1990 Transportation Act and the fact that that has not had any regulations promulgated. This is an area that could be regulated that needs to be. This was pointed out in our group as one of the main areas where contamination can occur and one of the main pieces in the feed safety chain that needs to be looked at.

We broke these out by industry segment. The thing that we talked about is in the industry segments the only segment that has formal regulation is the medicated feed licensed mill. The other segments of the industry do not have any formal regulation or guidelines. The only segment of the industry that has any formal enforcement again is the licensed feedmill.

Our discussion on point 3 I thought was very good. We felt some of the benefits of having a national

animal feed safety system would be to establish an official bar for all segments of the feed industry. Today there is an official bar for the licensed mill that's commonly understood. When you leave that there is no official bar.

We have a lot of various industry programs that have grown up in various portions of the business from ingredients to on-farm mixing, a lot of different programs. However, there's no common bar from which to evaluate them.

We felt like a program would have some benefit in international standards and international trade, something that could be commonly understood, a bar that everyone could understand.

Today the feed systems are only regulating less than 13 percent of the feed fed and we feel like a national feed program could get to the other areas that are not now being looked at.

Establish a reasonably based standard, focus resources. We felt this was a good approach. This was hit on before, that today the states are focussing primarily on economic issues--protein, fat, and fiber, if

we could reallocate those resources into a feed-based safety system and look at risk issues. Part of the discussion with the state people was how could we best partner with FDA in doing this? The states feel like they would need to be a partnering role, one that they could work with FDA in the development of a program.

We have some duplicate efforts today between the states. We talked about having labs perhaps that would focus on various feed safety aspects, rather than each state trying to do all they can with their given lab and their limited resources.

We talked about the whole approach needs to be holistic, and this is a new word for a lot of us. We looked it up. It's one that would be something that would encompass all the way from the ingredient all the way to the table.

We feel like enforcement is important. We need rapid enforcement. We need things to be enforced rather than to have rules and not enforce them, similar to what we have today in some of the ingredient issues, ingredients being marketed, especially when you get into

the areas of the herbs, and so forth, that are in feeds but they're not part of an AFCO definition.

We got into the 4 area that's been hit on. We felt that A through the recordkeeping and all these portions, really that FDA needs to get with the specific groups that those would involve. If we're talking recordkeeping, we shouldn't have people from a medicated feedmill talking about the kinds of records that would be appropriate for a renderer, and so forth, that FDA needs to get with these various groups when they have their meetings and partner with them and work with them in the development of those kinds of records that would be pieces of 4A on through 4F that would be appropriate for their kinds of businesses.

If we get into the enforcement area we had a lot of good discussion, I felt, there. One of the big ones is how do you inspect on farm? We only could point to like three states that have anything in their laws that enable them to go onto the farm. Some of them felt they could go on the farm through a federal-state inspection program but there it was only for cause; it's not a routine inspection. So we may need different kinds of

laws in order to have a system that encompasses our holistic type of approach.

We talked about purchasing agreements that today's feed manufacturers are trying to enforce, various standards on feed ingredient suppliers through the specifications that they establish, but this doesn't replace having some kind of a bar and inspection of those ingredient facilities for compliance with whatever bar they think is appropriate for their industry.

We hit a little bit on this FDA philosophy versus state and industry philosophy. We need to have a cooperative approach here, one that everybody works together.

Kinds of assurances--today we have licensing and we talked about well, what does licensing assure at the feedmill? Well, it puts them on a list for mandatory inspection. Does that assure anything?

We also talked about the fact that the Bioterrorism Act will give FDA a complete list for the first time of anyone handling foods. So we'll have a kind of a list that they can start with in order to make some evaluations of what to do with their programs.

So we have some identification, working with the local groups as far as to their segment of the feed industry, their processes, the types of controls, the bar, if you will, that needs to be established is a way to start.

I think the rest of this is redundant except for the one piece down here, that we need to have science-based identification of our hazards. I think there's some feeling today that everyone understands what the risks are, and we don't. We don't know what the risk are. When we get to dioxins, for example, we don't know what levels, we don't know what tolerances. Other contaminants, we don't know what levels are a problem. We need more information and then we need assays and analysis that will be able to be used by both the regulator and for the ingredient or feed manufacturer or whoever you might be on monitoring.

We don't have those tools today, so we need a scientific approach to establish what the risks are and then we need some ways of measuring and identification of them.

I think that's it. Anyone from the group have any additional comments?

MS. DUNNAVAN: Thank you very much.

[Applause.]

MS. DUNNAVAN: And for the record this is Bob Broyles.

We've finished the reports but I want to make sure to give everybody in the audience an opportunity to ask group 5A or 5B, if they have any questions.

Seeing no hands, I want to thank you all very much for the thoughtful and I think helpful information you've provided. You've worked really hard in your break-out groups and we really appreciate that.

I also want to thank the FDA volunteers that were facilitators and scribes for the break-out groups. I really appreciate that.

We're going to go to a break and then come back and conclude our meeting with next steps.

[Whereupon, at 2:41, the hearing was concluded.]

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